GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:3971
ANSWERED ON:09.04.2003
APPLICATIONS OF BIOTECH UNITS
GADDE RAMAMOHAN;M.V.V.S MURTHI

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the leading bio-tech units of Andhra Pradesh have submitted a number of applications to the Drugs Controller General of India;

(b) if so, the details thereof alongwith the time since when these are pending; and

(c) the action taken by DCGI for the clearance of these applications?

Answer

MINISTER OF HEALTH AND FAMILY WELFARE AND PARLIAMENTARY AFFAIRS (SMT. SUSHMA SWARAJ)

(a) Yes, Sir.

(b) & (c) : Unlike pharmaceuticals, r-DNA based therapeutics arerequired to be initially evaluated for by the Review Committee on Genetic Manipulation Clearance under Deptt. of Bio-technology. Thesafety and efficacy data generated with the proposed r-DNA base products are thereafter evaluated before the expert panel constituted for r-DNA based therapeutics in the office o f Drugs Controller General o f India, and Genetic Engineering Approval Committee under Ministry of Environment etc., before the final clearance is accorded.

Details of the proposals filed by Bio-tech units of Hyderabad in the office of DCG (I) alongwith the status of each application is given in Annexure.

Annexure referred to in reply to Lok Sabha Unstarred Question No. 3971 for 9.4.2003

Sr.No.	Name of the Firm	Date of application	Proposal For	Status
1.	M/s Bharat Bio-tech Int.Ltd. Hyderabad	17.05.99	Manufacture and Mar- keting of Indigenously developed r-Human Streptokinase	Under Clinical evaluation by the company
2.	M/s Shantha Bio-tech pvt.Ltd.	28.11.01	Manufacture and Mar- keting of Indigenously developed r-Human Streptokinase	Under Clinical evaluation by the company RCGM Clearance obtained on 10.03.03. Permission given for conducting the Clinical trial on 4.4.03
		11.2.2003	Manufacture and Mar- keting of Indigenously developed r-Human erythropoietin Inj.	
3.	M/s Dr. Reddy`s Labs, Hyderabad	28.05.01	Manufacturer and Mar- keting of Indigenously developed r-Human interferon alpha 2b	Under Clinical evaluation by the company
4.	M/s Biological E Ltd. Hyderabad	26.8.02	Manufacturer and Mar- keting of Indigenously developed r-Hepatitis B vaccine	Under Clinical evaluation by the company

5.M/s Virchow Bio-tech pvt.Ltd Hyderabad	19.12.02	Manufacturer and Marketing of Indigenously developed r-Human Interferon alpha 2b inj. 19.12.02 Interleukin inj. 17.12.02 Platelets derived growth factor,	RCGM clearance not yet obtained by the firm. In all the proposals, the Firm has been advised in Feb/march, 03 to get the facility inspected in conformity with GMP norms before the trial batches are produced.
6.M/s Medgene Bio-tech, Hyderabad	28.11.02	Manufacture and Marketing of indigenously developed r-Human growth Hormone	Firm has not submitted application as per prescribed norm. Firm was advised on 4.1.03 to make the application in the prescribed Form 40 along with requisite fees as per the rules.